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510(k) Summary

JAN 14 2011

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

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Contact Person:	Tim Thomas Vice President Regulatory Affairs & Quality Assurance Email: tim.thomas@givenimaging.com
Phone Number:	770-662-0870 ext. 1006
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Establishment Registration Number:	9710107
Date Prepared:	October 14, 2010
Device Trade Name(s):	Given PillCam® Platform with PillCam® SB Capsules with PillCam® SensorBelt
Device Common Name:	Ingestible telemetric gastrointestinal capsule imaging system
Classification:	Regulation No: 876.1300 Class: II Panel: Gastroenterology NEZ – System, Imaging, Gastrointestinal, Wireless, Capsule
Predicate Device(s):	Given PillCam® Platform with PillCam® SB Capsules with PillCam® SensorBelt ,(K091405) Given PillCam Platform with PillCam SB Capsules and Given AGILE Patency System (K090557)

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General Device Description:

The Given PillCam® Platform is comprised of three main subsystems; (1) the ingestible PillCam capsule, (2) the RAPID® software, and (3) the Given® Workstation and Hardware.

1. Ingestible PillCam Capsule

The disposable, ingestible PillCam Capsule is designed to acquire video images during the natural propulsion through the GI tract. The capsule transmits the acquired images via a RF communication channel to the DataRecorder located outside the body.

2 RAPID Software

The RAPID Software is a software application that is utilized to process, analyze, store, and view the acquired images collected from the DataRecorder to create a RAPID video of the images. The software also includes a reporting function to create detailed clinical reports, in-service training videos, and patient instruction forms.

3 Given Workstation and Hardware

The Workstation is a modified standard personal computer that is the operational platform for the RAPID software. The DataRecorder is an external receiving/recording unit that receives acquired images from the capsule. The PillCam® SensorBelt receives data from the PillCam capsule and transfers the data to the DataRecorder. The RAPID *Real Time* is a handheld device that allows for real-time viewing of acquired images through the GI tract. Other accessories include a flat panel LCD monitor, a high-capacity mass storage device, and a high-capacity USB portable storage device.

Intended Use:

SB Indications for Use:

The Given PillCam® Platform with the PillCam® SB Capsules is intended for visualization of the small bowel mucosa. It may be used as a tool in the detection of abnormalities of the small bowel in adults and children from two years of age.

The Suspected Blood Indicator (SBI) feature is intended to mark frames of the video suspected of containing blood or red areas.

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Technological Characteristics:	The technology characteristics are exactly the same as the predicate device.
Performance Data:	The device meets the guidance entitled "*Class II Special Controls Guidance Document: Ingestible Telemetric Gastrointestinal Capsule Imaging System; Final Guidance for Industry and FDA* dated November 28, 2001. Clinical validation test has been conducted in order to utilize PillCam® SensorBelt in overweight population with BMI greater than 30 kg/m^2, and supporting exclusion of overweight population warning statement in Given PillCam® Platform with PillCam® SB Capsules with PillCam® SensorBelt labeling. The validation clinical test was conducted with twenty five healthy volunteers who underwent the SB procedure using PillCam®SB2 capsule, a DR2 DataRecorder, and a PillCam® SensorBelt. There had no multiple ingestions, and each of the twenty five healthy volunteers ingested a separate PillCam® SB2 capsule There are no new risks raised by utilizing PillCam® SensorBelt in overweight population of BMI $\geq$ 30kg/m^2. The performance of the SensorBelt has not been studied in patients with BMI greater than 43.3.The clinical validation data presented in details in Section 20 - Performance Testing Clinical of this Traditional 510(k) Notification has shown substantial equivalence to the predicate device.
Conclusion:	Based on the clinical validation data Given Imaging believes that Given PillCam® Platform with PillCam® SB Capsules with PillCam® SensorBelt and the predicate devices selected are substantially equivalent and do not change the fundamental scientific technology and intended use of the market-cleared devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Tim Thomas
Vice President, Regulatory Affairs
& Quality Assurance
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JAN 14 2011

Re: K103088
Trade/Device Name: Given PillCam® Platform with PillCam® SB Capsules with PillCam® SensorBelt
Regulation Number: 21 CFR §876.1300
Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system
Regulatory Class: II
Product Code: NEZ
Dated: January 4, 2011
Received: January 7, 2011

Dear Mr. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K103088

Device Name: Given PillCam® Platform with PillCam® SB Capsules with PillCam® SensorBelt

Indications for Use:

SB Indications for Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103088